# Medical Pharmacy Drug Prior Authorization Criteria

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|---|---|---|---|
| **Drug Trade Name:** | Neulasta, Fulphila, Udenyca, Ziextenzo, Nyvepria | **Drug Generic Name:** | Pegfilgrastim |
| **J Code:** | J2506, Q5108, Q5111, Q5120, Q5122, Q5127 | **1 billable unit =** | 0.5 mg |
| **Original Date of Review:** | 12/7/2022 | **Last Reviewed:** | 6/12/2024 |
| **Revision Date History** | 12/7/2022, 3/15/2023, 12/13/2023, 6/12/2024 | | |

Pegfilgrastim is a colony stimulating factor that acts on hematopoietic cells by binding to specific cell surface receptors thereby stimulating proliferation, differentiation, commitment, and end cell functional activation

**Criteria:**

- **Length of authorization:**
  - Bone marrow transplantation (BMT) failure or engraftment delay: Coverage will be provided for 1 dose only and may not be renewed.
  - Peripheral blood progenitor cell (PBPC) mobilization and transplant: Coverage will be provided for 1 dose only and may not be renewed.
  - All other indications: Coverage will be provided for four months and may be renewed unless otherwise specified.
- **Age: see below for product specific requirements**
- **Diagnoses [including ICD-10 codes]: see below**
- **Quantity Limit:**
  - Neulasta 6 mg prefilled syringe: 1 syringe per 14 days
  - Neulasta Onpro kit: 1 kit per 14 days
  - Fulphila 6 mg prefilled syringe: 1 syringe per 14 days
  - Stimufend 6mg prefilled syringe; 1 syringe per 14 days
  - Udenyca 6 mg prefilled syringe: 1 syringe per 14 days
  - Udenyca 6 mg Onbody kit: 1 kit per 14 days
  - Udenyca 6mg prefilled autoinjector: 1 pen per 14 days
  - Ziextenzo 6 mg prefilled syringe: 1 syringe per 14 days
  - Nyvepria 6 mg prefilled syringe: 1 syringe per 14 days
  - Fylnetra 6 mg prefilled syringe: 1 syringe per 14 days
- **Maximum Units:**

| Indication | Billable Units |
|---|---|
| Acute radiation exposure | 12 billable units weekly x 2 doses |
| BMT failure or engraftment delay/PBPC mobilization and transplant | 12 billable units weekly x 1 dose |
| All other indications | 12 billable units per 14 days |

- **Initial Approval Criteria**
  - **Indication Specific Criteria**
    - **Prophylactic use in patients with solid tumors or non-myeloid malignancy**

- Patient is undergoing treatment regimen that National Comprehensive Cancer Network recommends inclusion of pegfilgrastim as standard of care.
- Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia* of greater than 20%, OR
- Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia* of 10% to 20% AND one or more of the following co-morbidities:
    - Age >65 years receiving full dose intensity chemotherapy
    - Extensive prior exposure to chemotherapy
    - Previous exposure of pelvis, or other areas of large amounts of bone marrow, to radiation
    - Persistent neutropenia (ANC ≤ 1000/mm3)
    - Bone marrow involvement by tumor
    - Patient has a condition that can potentially increase the risk of serious infection (i.e., HIV/AIDS with low CD4 counts)
    - Recent surgery and/or open wounds
    - Poor performance status
    - Renal dysfunction (creatinine clearance <50 mL/min)
    - Liver dysfunction (elevated bilirubin >2.0 mg/dL)
    - Chronic immunosuppression in the post-transplant setting, including organ transplant
    - Note: Dose-dense therapy, in general, requires growth factor support to maintain dose intensity and schedule. In the palliative setting, consideration should be given to dose reduction or change in regimen.

- **Patient who experience a neutropenic complication from a prior cycle of the same chemotherapy**
    - Note: Dose-dense therapy, in general, requires growth factor support to maintain dose intensity and schedule. In the palliative setting, consideration should be given to dose reduction or change in regimen.
- **Patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Acute Radiation Syndrome [H-ARS])**
- **Bone marrow transplantation (BMT) failure or engraftment delay**
- **Peripheral blood progenitor cell (PBPC) mobilization and transplant**
- **Wilms Tumor (Nephroblastoma)**

- **Renewal Criteria**
    - Note: Coverage for use in BMT failure or engraftment delay and PBPC mobilization and transplant may NOT be renewed.
    - Coverage for all other indications can be renewed based upon the following criteria:
        - Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in universal criteria; AND
        - Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: splenic rupture, acute respiratory distress syndrome (ARDS), serious allergic reactions/anaphylaxis, sickle cell crisis, glomerulonephritis, leukocytosis, thrombocytopenia, capillary leak syndrome, potential for tumor growth stimulation of malignant cells, aortitis, myelodysplastic syndrome and acute myeloid leukemia, etc.

- **Dosage/Administration**

| **Pegfilgrastim** | |
|---|---|
| **Indication** | **Dose** |
| Prophylactic use in patients with non-myeloid malignancy<br>Patient who experienced a neutropenic complication from a prior cycle of the same chemotherapy | • 6 mg subcutaneously once per chemotherapy cycle and dosed no more frequently than every 14 days<br>• For pediatric patients weighing <45 kg:<br>○ <10 kg = 0.1 mg/kg<br>○ 10-20 kg = 1.5 mg<br>○ 21-30 kg = 2.5 mg<br>31-44 kg = 4 mg |
| Acute Radiation Exposure (Hematopoietic Acute Radiation Syndrome) | • 6 mg subcutaneously weekly x 2 doses<br>• For pediatric patients weighing <45 kg:<br>○ <10 kg = 0.1 mg/kg<br>○ 10-20 kg = 1.5 mg<br>○ 21-30 kg = 2.5 mg<br>• 31-44 kg = 4 mg |
| BMT failure or engraftment delay<br>PBPC mobilization and transplant | • 6 mg subcutaneously for 1 dose only |

**NDC:**

- Neulasta 6 mg prefilled syringe: 55513-0190-xx
- Neulasta 6 mg prefilled syringe Onpro Kit: 55513-0192-xx
- Fulphila 6 mg prefilled single-dose syringe: 67457-0833-xx
- Udenyca 6 mg prefilled single-dose syringe: 70114-0101-xx
- Udenyca 6mg prefilled syringe Onbody kit: 70114-0130-xx
- Udenyca 6mg prefilled autoinjector: 70114-0120-xx
- Ziextenzo 6 mg single-dose prefilled syringe: 61314-0866-xx
- Nyvepria 6 mg single-dose prefilled syringe: 00069-0324-xx
- Fylnetra 6 mg single-dose prefilled syringe: 70121-1627-xx
- Stimufend 6 mg single-dose prefilled syringe: 65219-0371-xx

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**Appendix 1 – Covered Diagnosis Codes**

| ICD-10 | ICD-10 Description |
|---|---|
| D61.81 | Pancytopenia |
| C64.1 | Malignant neoplasm of right kidney, except renal pelvis |
| C64.2 | Malignant neoplasm of left kidney, except renal pelvis |
| C64.9 | Malignant neoplasm of unspecified kidney, except renal pelvis |
| D70.1 | Agranulocytosis secondary to cancer chemotherapy |
| D70.9 | Neutropenia, unspecified |
| T45.1X5A | Adverse effect of antineoplastic and immunosuppressive drugs initial encounter |
| T45.1X5D | Adverse effect of antineoplastic and immunosuppressive drugs subsequent encounter |
| T45.1X5S | Adverse effect of antineoplastic and immunosuppressive drugs sequela |
| T66.XXXA | Radiation sickness, unspecified, initial encounter |
| T66.XXXD | Radiation sickness, unspecified, subsequent encounter |
| T66.XXXS | Radiation sickness, unspecified, sequela |
| W88.1 | Exposure to radioactive isotopes |
| W88.8 | Exposure to other ionizing radiation |
| Z41.8 | Encounter for other procedures for purposes other than remedying health state |
| Z48.290 | Encounter for aftercare following bone marrow transplant |
| Z51.11 | Encounter for antineoplastic chemotherapy |
| Z51.12 | Encounter for antineoplastic immunotherapy |
| Z51.89 | Encounter for other specified aftercare |
| Z52.011 | Autologous donor, stem cells |
| Z76.89 | Persons encountering health services in other specified circumstances |
| Z94.81 | Bone marrow transplant status |
| Z94.84 | Stem cells transplant status |